S. 250

To reduce the costs of prescription drugs for Medicare beneficiaries and to guarantee access to comprehensive prescription drug coverage under part D of the Medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

January 10, 2007

Ms. Snowe (for herself and Mr. Wyden) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To reduce the costs of prescription drugs for Medicare beneficiaries and to guarantee access to comprehensive prescription drug coverage under part D of the Medicare program, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Medicare Enhance-
- 5 ments for Needed Drugs Act of 2007".

SEC. 2. GAO STUDIES AND REPORTS ON PRICES OF PRE-2 SCRIPTION DRUGS. 3 (a) REVIEW AND REPORTS ON RETAIL PRICES OF 4 Prescription Drugs.— 5 (1) Initial review.—The Comptroller General 6 of the United States shall conduct a review of the 7 retail cost of prescription drugs in the United States 8 during 2000 through 2006, with an emphasis on the 9 prescription drugs most utilized for individuals age 10 65 or older. (2) Subsequent review.—After conducting 11 12 the review under paragraph (1), the Comptroller 13 General shall continuously review the retail cost of 14 such drugs through December 31, 2010, to deter-15 mine the changes in such costs. 16 (3) Reports.— (A) Initial review.—Not later than 90 17 18 days after the date of enactment of this Act, 19 the Comptroller General shall submit to Con-20 gress a report on the initial review conducted 21 under paragraph (1). 22 Subsequent review.—Not 23 than April 1 of 2008, 2009, 2010, and 2011, 24 the Comptroller General shall submit to Con-25 gress a report on the subsequent review con-

ducted under paragraph (2).

1	(b) Annual GAO Study and Report on Retail
2	AND ACQUISITION PRICES OF CERTAIN PRESCRIPTION
3	Drugs.—
4	(1) Ongoing study.—The Comptroller Gen-
5	eral of the United States shall conduct an ongoing
6	study that compares the average retail cost in the
7	United States for each of the 20 most utilized pre-
8	scription drugs for individuals age 65 or older
9	with—
10	(A) the average price at which private
11	health plans acquire each such drug;
12	(B) the average price at which the Depart-
13	ment of Defense under the Defense Health Pro-
14	gram acquires each such drug;
15	(C) the average price at which the Depart-
16	ment of Veterans Affairs under the laws admin-
17	istered by the Secretary of Veterans Affairs ac-
18	quires each such drug; and
19	(D) the average negotiated price for each
20	such drug that eligible beneficiaries enrolled in
21	a prescription drug plan under part D of title
22	XVIII of the Social Security Act that provides
23	only basic prescription drug coverage have ac-
24	cess to under such plans.

1	(2) ANNUAL REPORT.—Not later than October
2	1, 2007, and annually thereafter, the Comptroller
3	General shall submit to Congress a report on the
4	study conducted under paragraph (1), together with
5	such recommendations as the Comptroller General
6	determines appropriate.
7	SEC. 3. INCLUSION OF AVERAGE AGGREGATE BENEFICIARY
8	COSTS AND SAVINGS IN COMPARATIVE IN-
9	FORMATION FOR BASIC MEDICARE PRE-
10	SCRIPTION DRUG PLANS.
11	Section 1860D–1(c)(3) of the Social Security Act (42
12	U.S.C. 1395w-101(c)(3)) is amended—
13	(1) in subparagraph (A)—
14	(A) in the matter preceding clause (i), by
15	striking "subparagraph (B)" and inserting
16	"subparagraphs (B) and (C)"; and
17	(B) by adding at the end the following new
18	clause:
19	"(vi) Average aggregate bene-
20	FICIARY COSTS AND SAVINGS.—With re-
21	spect to plan years beginning on or after
22	January 1, 2008, the average aggregate
23	costs, including deductibles and other cost-
24	sharing, that a beneficiary will incur for
25	covered part D drugs in the year under the

1	plan compared to the average aggregate
2	costs that an eligible beneficiary with no
3	prescription drug coverage will incur for
4	covered part D drugs in the year."; and
5	(2) by adding at the end the following new sub-
6	paragraph:
7	"(C) Average aggregate beneficiary
8	COSTS AND SAVINGS INFORMATION ONLY FOR
9	BASIC PRESCRIPTION DRUG PLANS.—The Sec-
10	retary shall not provide comparative informa-
11	tion under subparagraph (A)(vi) with respect
12	to—
13	"(i) a prescription drug plan that pro-
14	vides supplemental prescription drug cov-
15	erage; or
16	"(ii) a Medicare Advantage plan.".
17	SEC. 4. NEGOTIATING FAIR PRICES FOR MEDICARE PRE-
18	SCRIPTION DRUGS.
19	(a) In General.—Section 1860D–11 of the Social
20	Security Act (42 U.S.C. 1395w-111) is amended by strik-
21	ing subsection (i) (relating to noninterference) and by in-
22	serting the following:
23	"(i) AUTHORITY TO NEGOTIATE PRICES WITH MAN-
24	UFACTURERS.—

"(1) In general.—In order to ensure that 1 2 beneficiaries enrolled under prescription drug plans 3 and MA-PD plans pay the lowest possible price, the 4 Secretary shall have authority similar to that of 5 other Federal entities that purchase prescription 6 drugs in bulk to negotiate contracts with manufac-7 turers of covered part D drugs, consistent with the 8 requirements and in furtherance of the goals of pro-9 viding quality care and containing costs under this 10 part. "(2) 11 MANDATORY RESPONSIBILITIES.—The 12 Secretary shall be required to—

- - "(A) negotiate contracts with manufacturers of covered part D drugs when the drug is a single source drug without a therapeutic equivalent;
 - "(B) participate in the negotiation of contracts with respect to any covered part D drug upon the request of an approved prescription drug plan or MA-PD plan;
 - "(C) participate in the negotiation of contracts for any covered part D drugs for which there is a substantial amount of Federal research funding in the development of the drug; and

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"(D) negotiate contracts with manufacturers of covered part D drugs for each standard fallback prescription drug plan under subsection (g) and each comprehensive fallback prescrip-

tion drug plan under subsection (k).

- "(3) RULE OF CONSTRUCTION.—Nothing in paragraph (2) shall be construed to limit the authority of the Secretary under paragraph (1) to the mandatory responsibilities under paragraph (2).
 - "(4) NO PARTICULAR FORMULARY OR PRICE STRUCTURE.—In order to promote competition under this part and in carrying out this part, the Secretary may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.
 - "(5) USE OF SAVINGS.—The savings to the Medicare Prescription Drug Account through the use of the authority provided under this subsection (including the mandatory responsibilities under paragraph (2)) shall be used to strengthen the program under this part and to reduce the Federal deficit.".
- 23 (b) EFFECTIVE DATE.—The amendment made by 24 this section shall take effect on the date of enactment of 25 this Act.

1	SEC. 5. ACCESS TO A COMPREHENSIVE MEDICARE PRE-
2	SCRIPTION DRUG PLAN.
3	(a) Requirement for Access.—Section 1860D—
4	3(a) of the Social Security Act (42 U.S.C. 1395w-103(a))
5	is amended—
6	(1) in paragraph (1)—
7	(A) by striking "Choice of at least
8	TWO PLANS IN EACH AREA.—The Secretary"
9	and inserting "CHOICE
10	"(A) CHOICE OF AT LEAST TWO PLANS IN
11	EACH AREA.—The Secretary"; and
12	(B) by adding at the end the following new
13	subparagraph:
14	"(B) Choice of a comprehensive pre-
15	SCRIPTION DRUG PLAN.—In addition to the re-
16	quirement under subparagraph (A), the Sec-
17	retary shall ensure that each part D eligible in-
18	dividual has available a choice of enrollment in
19	a comprehensive prescription drug plan (as de-
20	fined in paragraph (4)) in the area in which the
21	individual resides. In any such case in which
22	such a plan is not available, the part D eligible
23	individual shall be given the opportunity to en-
24	roll in a comprehensive fallback prescription
25	drug plan."; and

- 1 (2) by adding at the end the following new 2 paragraph:
- 3 Comprehensive PRESCRIPTION DRUG 4 PLAN.—For purposes of this section, the term 'com-5 prehensive prescription drug plan' means a prescrip-6 tion drug plan that provides coverage of covered part 7 D drugs after an individual has reached the initial 8 coverage limit under paragraph (3) of section 9 1860D-2(b) but has not reached the annual out-of-10 pocket threshold under paragraph (4)(B) of such 11 section that is the same as the coverage for such 12 drugs that is provided under the plan after the indi-13 vidual has met the deductible under paragraph (1) 14 of such section but has not reached such initial cov-15 erage limit.".
- 16 (b) Comprehensive Fallback Prescription 17 Drug Plan.—Section 1860D–11 of the Social Security
- 18 Act (42 U.S.C. 1395w-111) is amended by adding at the
- 19 end the following new subsection:
- 20 "(k) Guaranteeing Access to Comprehensive
- 21 Coverage.—
- 22 "(1) Solicitation of Bids.—Separate from
- 23 the bidding process under subsections (b) and (g),
- the Secretary shall provide for a process for the so-
- 25 licitation of bids from eligible comprehensive fallback

1 entities (as defined in paragraph (2)) for the offer-2 ing in all comprehensive fallback service areas (as 3 defined in paragraph (3)) in one or more PDP re-4 gions of a comprehensive fallback prescription drug 5 plan (as defined in paragraph (4)) during the con-6 tract period specified in subsection (g)(5) (as made 7 applicable to this subsection under paragraph (6)). 8 "(2) Eligible comprehensive fallback en-9 TITY.—For purposes of this section, the term 'eligible comprehensive fallback entity' means, with re-10 11 spect to all comprehensive fallback service areas in 12 a PDP region for a contract period, an entity that— "(A) meets the requirements to be a PDP 13 14 sponsor (or would meet such requirements but 15 for the fact that the entity is not a risk-bearing 16 entity); and 17 "(B) does not submit a bid under section 18 1860D–11(b) for any prescription drug plan for 19 any PDP region for the first year of such con-20 tract period. 21 For purposes of subparagraph (B), an entity shall be treated as submitting a bid with respect to a pre-22 23 scription drug plan if the entity is acting as a sub-24 contractor of a PDP sponsor that is offering such a

plan. The previous sentence shall not apply to enti-

- 1 ties that are subcontractors of an MA organization 2 except insofar as such organization is acting as a 3 PDP sponsor with respect to a prescription drug 4 plan.
- 5 "(3) Fallback service area.—For purposes 6 of this subsection, the term 'comprehensive fallback 7 service area' means, for a PDP region with respect 8 to a year, any area within such region for which the 9 Secretary determines before the beginning of the 10 year that the access requirements of the first sentence of section 1860D-3(a)(1)(B) will not be met 12 for part D eligible individuals residing in the area 13 for the year.
 - "(4) Comprehensive fallback prescrip-TION DRUG PLAN.—For purposes of this part, the term 'comprehensive fallback prescription drug plan' means a prescription drug plan that—
 - "(A) offers the standard prescription drug coverage and access to negotiated prices described in section 1860D-2(a)(1)(A);
 - "(B) offers coverage of covered part D drugs after an individual has reached the initial coverage limit under paragraph (3) of section 1860D-2(b) but has not reached the annual out-of-pocket threshold under paragraph (4)(B)

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1	of such section that is the same as the coverage
2	for such drugs that is offered after the indi-
3	vidual has met the deductible under paragraph
4	(1) of such section but has not reached such
5	initial coverage limit; and
6	"(C) meets such other requirements as the
7	Secretary may specify.
8	"(5) Monthly Beneficiary Premium.—Ex-
9	cept as provided in section 1860D–13(b) (relating to

"(5) Monthly beneficiary premium.—Except as provided in section 1860D–13(b) (relating to late enrollment penalty) and subject to section 1860D–14 (relating to low-income assistance), the monthly beneficiary premium to be charged under a comprehensive fallback prescription drug plan offered in all comprehensive fallback service areas in a PDP region shall be uniform and shall be an amount equal to—

"(A) 25.5 percent of an amount equal to the Secretary's estimate of the average monthly per capita actuarial cost, including administrative expenses, under the comprehensive fallback prescription drug plan of providing the coverage described in paragraph (4)(A) in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services; and

"(B) 100 percent of an amount equal to the Secretary's estimate of the average monthly per capita actuarial cost, including administra-tive expenses, under the comprehensive fallback prescription drug plan of providing the coverage described in paragraph (4)(B) in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services.

In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not standard or comprehensive fallback prescription drug plans.

- "(6) Incorporation of standard fallback prescription drug plan provisions.—The provisions of paragraphs (1)(B), (5), and (7) of subsection (g) shall apply to comprehensive fallback prescription drug plans and entities offering such plans in the same manner as such provisions apply to standard fallback prescription drug plans and entities offering such plans.
- "(7) SAME ENTITY MAY OFFER BOTH FALL-BACK PRESCRIPTION DRUG PLANS IN AN AREA.— The Secretary may award a contract to an entity under this subsection with respect to an area and

1	period and a contract under subsection (g) with re-
2	spect to the same area and period.".
3	(c) Conforming Amendments.—
4	(1) Access.—Section 1860D-3 of the Social
5	Security Act (42 U.S.C. 1395w-103) is amended—
6	(A) in subsection (a)—
7	(i) in paragraph (1)(A) of subsection
8	(a), as redesignated by subsection (a), by
9	inserting "standard" before "fallback";
10	(ii) in paragraph (2), by striking
11	"paragraph (1)" and inserting "paragraph
12	(1)(A)"; and
13	(B) in subsection (b)(2), by striking "fall-
14	back prescription drug plan for that area under
15	section 1860D-11(g)" and inserting "standard
16	or comprehensive fallback prescription drug
17	plan for that area under subsections (g) and (k)
18	of section 1860D–11, as applicable".
19	(2) Limited Risk Plans.—Section 1860D-
20	11(f) of the Social Security Act (42 U.S.C. 1395w-
21	111(f)) is amended—
22	(A) in paragraph (1)—
23	(i) by striking "1860D-3(a)" and in-
24	serting "1860D-3(a)(1)(A)"; and

1	(ii) by inserting "standard" before
2	"fallback"; and
3	(B) in paragraph (2)(A), by striking
4	"1860D-3(a)" and inserting "1860D-
5	3(a)(1)(A)"; and
6	(C) in each of subparagraphs (A) and (B)
7	of paragraph (4), by striking "a fallback" and
8	inserting "a standard or comprehensive fall-
9	back''.
10	(3) Standard fallback prescription drug
11	PLAN.—Section 1860D-11(g) of the Social Security
12	Act (42 U.S.C. 1395w-111(g)) is amended—
13	(A) in the heading, by inserting "STAND-
14	ARD PRESCRIPTION DRUG" after "Access to";
15	(B) by inserting "STANDARD" before
16	"FALLBACK" each place it appears;
17	(C) by striking "FALLBACK" each place it
18	appears and inserting "STANDARD FALLBACK";
19	(D) by inserting "standard" before "fall-
20	back" each place it appears; and
21	(E) in paragraph (3), by striking "1860D-
22	3(a)" and inserting " $1860D-3(a)(1)(A)$ ".
23	(4) Annual Report.—Section 1860D-11(h) of
24	the Social Security Act (42 U.S.C. 1395w–111(h)) is

1	amended by striking "(f) and (g)" and inserting
2	"(f), (g), and (k)".
3	(5) Limitation on entities offering fall-
4	BACK PRESCRIPTION DRUG PLANS.—Section 1860D-
5	12(b)(2) of the Social Security Act (42 U.S.C.
6	1395w-112(b)(2)) is amended—
7	(A) in the matter preceding subparagraph
8	(A), by striking "a fallback" and inserting "a
9	standard or comprehensive fallback";
10	(B) in subparagraph (A)—
11	(i) by striking "section 1860D-11(g)"
12	and inserting "subsection (g) or (k) of sec-
13	tion 1860D–11'';
14	(ii) by striking "such section" and in-
15	serting "such subsections, as applicable"
16	and
17	(iii) by striking "a fallback" and in-
18	serting "a standard or comprehensive fall-
19	back'';
20	(C) in subparagraph (B), by striking "a
21	fallback" and inserting "a standard or com-
22	prehensive fallback'';
23	(D) in subparagraph (C), by striking "a
24	fallback" and inserting "a standard or com-
25	prehensive fallback' and

- 1 (E) in the flush matter following subpara-2 graph (C), by striking "a fallback" and insert-3 ing "a standard or comprehensive fallback".
- 4 (6) COLLECTION OF PREMIUM.—Section
 5 1860D-13(c)(3) of the Social Security Act (42
 6 U.S.C. 1395w-113(c)(3)) is amended by striking "a
 7 fallback" and inserting "a standard or comprehen8 sive fallback".
 - (7) Payment.—Section 1860D–15(g) of the Social Security Act (42 U.S.C. 1395w–115(g)) is amended by striking "offering" and all that follows and inserting the following: "offering.—
 - "(1) a standard prescription drug plan (as defined in paragraph (4) of section 1860D–11(g)), the amount payable shall be the amounts determined under the contract for such plan pursuant to paragraph (5) of such section; and
 - "(2) a comprehensive prescription drug plan (as defined in paragraph (4) of section 1860D–11(k)), the amount payable shall be the amounts determined under the contract for such plan pursuant to such paragraph (5) (as made applicable to section 1860D–11(k) under paragraph (6) of such section)."

1	(8) Payment from account.—Section
2	1860D–16(b)(1)(B) of the Social Security Act (42
3	U.S.C. $1395w-116(b)(1)(B)$ is amended by insert-
4	ing "standard and comprehensive" before "fall-
5	back".
6	(9) Definition.—Section 1860D-41(a)(5) of
7	the Social Security Act (42 U.S.C. 1395w-
8	151(a)(5)) is amended to read as follows:
9	"(5) STANDARD FALLBACK PRESCRIPTION
10	DRUG PLAN; COMPREHENSIVE FALLBACK PRESCRIP-
11	TION DRUG PLAN.—The terms 'standard fallback
12	prescription drug plan' and 'comprehensive fallback
13	prescription drug plan' have the meaning given those
14	terms in subsection (g)(4) and (k)(4), respectively,
15	of section 1860D–11.".
16	(d) Effective Date.—The amendments made by
17	this section shall take effect on January 1, 2008.

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